Please amend the claims without prejudice to or disclaimer of the subject matter therein:

Please cancel claims 1-14.

AMENDMENTS TO THE SPECIFICATION

Please amend the specification as follows:

Page 10, Table 1, row 4, change: "2.0 mm OD" " to --5.0 mm OD --.

Page 12, line 19, change: "so as secure" to --so as to secure--.

Page 14, line 11, change: "so as minimize" to --so as to minimize--.

REMARKS

Applicant has considered the Final, and reviewed this Application in view thereof. In the Final, the Office objected to the drawings and specification, confirmed previously allowed Claims 15-20, but rejected Claims 1-14 over additional references not previously cited. Claims 1-14 are cancelled without prejudice to or disclaimer of the subject matter therein, in favor of at least one later-filed divisional, continuation or continuation-in-part directed thereto. Thus, only claims 1-14 remain pending.

Applicant hereby amends the specification to correct typographical/grammatical errors therein. These amendments do not introduce new matter.

Applicants prior, January 22, 2004, Amendment proposed amendment of Figures 1, 2D and 10, all of which Applicant submitted to overcome respective objections earlier presented (see July 25, 2003, Office Action). From the Office's Final comments, Applicant infers that Applicant's the prior proposed drawing amendments addressed all prior objections.

The Final objected to: i) the drawings, stating they must show a "handle means removably coupled to the cannula"; and ii) to the specification, as failing to "provide antecedent basis for a

handle means removably coupled to the cannula". Applicant respectfully disagrees with the Office's position.

The specification (specifically, page 5, lines 8-10, and page 10, line 16-page 11, line 1) particularly discloses: "a handle means, removably coupled to at least one of the biopsy device and cannula"; and "a handle means... removably coupled to the placement means". More specifically, the specification (page 13, lines 6-10) discloses an exemplary biopsy device, cannula, or both comprising a "leuer-type coupler, the leuer-type coupler being removably coupled to the biopsy device or cannula and capable of removably coupling to the handle means". Applicants respectfully submit that the specification does, indeed, provide proper antecedent basis for a handle means removably coupled to the cannula, and more particularly, provides a representative, non-limiting preferred leuer-type coupler serving to achieve this with the disclosed tool.

Alternatively, the specification (page 16, line 18–page 17, line 1) discloses a handle 12 with a split collet configuration 30 (see, Fig. 4C) on its distal end. The handle is connected to the biopsy cannula 18 by a locking nut 15 that compresses the split collet 30 against the outside surface of the biopsy device 18, thereby removably coupling the handle to the biopsy device. Such representative, preferred removable coupling provides antecedent basis for the method (and previously, device) claimed. Moreover, the drawings represent (*e.g.*, Fig. 1) coaxial placement of access cannula 21 over biopsy cannula 18 using access handle 12. Any such placement, as shown, could not be achieved absent a removable coupling. Applicant submits that the drawings represent each and every claimed element, and that the specification does provide proper antecedent basis for the claimed invention, and respectfully requests the Office reconsider and withdraw the objection to both the drawings and specification.

Applicant attached formal drawings, Figures 1, 2D and 10, previously provisionally amended. Upon receipt of the Office's formal Notice of Allowance of pending claims 15-20, Applicant will correct and timely file complete formal drawings prior to payment of the Issue Fee.

The Office rejected claims 1, 2, 4-8, 10, 11 and 14 under 35 U.S.C. §102(e) as anticipated by published U.S. Patent Application No. 2003/0004530 to Reo ("Reo"). In addition, the Office rejected claims 3-9 under 35 U.S.C. §103(a) over Reo (as applied in the Office's 35 U.S.C. §102(e) anticipatory rejection of claims 1, 4, 7 and 8), and claims 12 and 13 under 35 U.S.C. §103(a) over Reo (as applied in the Office's 35 U.S.C. §102(e) anticipatory rejection of claims 1 and 4) and further in view of U.S. Patent No. 5,954,671 to O'Neill.

Substantively, Reo discloses, *inter alia*, a first instrument 12, which functions as an obturator (page 2, paragraph 0052, line 1); a second instrument 14, which functions as a cannula or guide sheath; and a handle 18 having a first and second sockets 80 and 86, respectively (page 3, paragraphs 0068-69, *et seq.*). The first and second sockets are placed in a close side-by-side relationship along the main axis of the handle (page 5, paragraph 85, lines 4-5), and the first, obturator instrument, and a drill bit instrument (below) fit inside, but do not mesh with the second socket 86 (page 7, paragraph 0072, lines 2-3). In addition, Reo discloses a drill bit instrument 16 (page 3, paragraph 60), and a possible diagnostic or therapeutic element 110, which may comprise a biopsy instrument (page 7, paragraph 0123, lines 1-5).

Reo discloses use of the foregoing first, second and drill bit instruments: positioning the first obturator instrument (slip-fit with the handle's first socket) by penetrating soft tissue and securing a desired position in a patient pedicle. A user then removes the handle from the so-positioned first obturator instrument, slip-fits the second instrument to the handle's second socket and similarly positions the second instrument over the first obturator instrument in the pedicle. Next, the user removes the handle from the second instrument, similarly engages the handle's first socket with the drill bit instrument and advances the cutting edge of the drill bit instrument, opening a passage completely through into the cancellous bone; thereafter, removing the drill bit instrument and guide pin component, leaving only the second instrument in place, and providing an access passage 158 to the cancellous bone through which a user can perform various functions using a catheter component, or a diagnostic or therapeutic element, such as a biopsy instrument to obtain samples of cancellous bone. (See, page 5, paragraph 0100-page 7, paragraph 123.)

The Office asserts that Reo discloses a "biopsy device (12 or 16)". Applicant respectfully disagrees. Reo's 12 is an obturator instrument for penetrating and separating tissue and bone. Reo's 16 is a drill bit instrument for opening a passage completely through into cancellous bone. The combined use of 12 and 16 eliminates any chance of obtaining a biopsy sample, and in fact, Reo specifically requires that a user place a biopsy instrument 110 **through** a second instrument into a passage created by application and removal of the obturator and drill bit instruments. Applying Applicant's language, Reo's biopsy device telescopes **within** a second instrument. Contrary to the Office's position, Reo does not disclose Applicant's novel tool, which innovatively integrates a biopsy device's and access cannula's function so as to entirely eliminate use of, as the very least, an obturator and/or drill bit instruments, such as are required by Reo.

Furthermore, Reo teaches a slip-fit handle and method significantly differentiated from Applicant's novel tool and claimed method, and provides no suggestion or motivation to disregard its disparate teachings, Reo fails to render Applicant's novel tool and claimed method obvious, the latter, as the Office has acknowledged. Additionally, Applicant addresses in detail the failed teachings of O'Neill in Applicant's response to the Office's July 25, 2003, Office Action, the substance of which is incorporated herein in its entirety. Even O'Neill, teaching the exact opposite of Applicant's novel tool and method, and failing to provide motivation to disregard such teachings, fails to supplant Reo's deficiencies so as to render Applicant's tool and resulting method obvious.

And, finally, Reo has a filing date of August 26, 2002, more than six months after Applicant's filing date, and almost ten months after Applicant's priority filing date, October 30, 2001. Therefore, as a purely technical matter, Reo does not meet the statutory requirements of 35 U.S.C. §102(e), as it is not an application for patent "by another filed in the United States before the invention by the applicant". Therefore, on the foregoing bases, Reo neither anticipates, nor renders obvious (alone or in combination with O'Neill) Applicant's novel tool.

Applicant therefore respectfully submits that Applicant's tool are novel and unobvious, over Reo and O'Neill, and requests that the Office reconsider these rejections and avoid raising them in

any subsequently-filed divisional, continuation or continuation-in-part application having claims directed to the subject matter of cancelled claims 1-14.

In view of the foregoing Amendment and Remarks, Applicant requests that the Office promptly issue a notice of allowance directly to allowed claims 15-20.

Applicant files contemporaneously herewith a Small Entity Petition for Extension of Time Under 37 C.F.R. §1.136(a) and Transmittal of Fee Under 37 C.F.R. §1.17, including Check No. 2267 in the amount of four hundred ninety U.S. dollars ($490.00 US) in payment of an Extension Fee for response within the third month pursuant to §1.136(a). If the Office should have any questions concerning this communication or the Petition, deems a personal interview helpful, or identifies any additional fees, not contemporaneously or previously paid to maintain this pending application, Applicant asks that the Office promptly telephone Applicant at: 715.389.2619; or alternatively, Applicant's undersigned Attorney at: 206.283.1665.

Respectfully submitted,

Stephen Faciszewski

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Date: October 18, 2004

SEPARATE VERSION OF REWRITTEN CLAIMS

UNDER 37 C.F.R. §1.121(c)(i)

1. (Currently cancelled without prejudice or disclaimer.)
2. (Currently cancelled without prejudice or disclaimer.)
3. (Currently cancelled without prejudice or disclaimer.)
4. (Currently cancelled without prejudice or disclaimer.)
5. (Currently cancelled without prejudice or disclaimer.)
6. (Currently cancelled without prejudice or disclaimer.)
7. (Currently cancelled without prejudice or disclaimer.)
8. (Currently cancelled without prejudice or disclaimer.)
9. (Currently cancelled without prejudice or disclaimer.)
10. (Currently cancelled without prejudice or disclaimer.)
11. (Currently cancelled without prejudice or disclaimer.)
12. (Currently cancelled without prejudice or disclaimer.)
13. (Currently cancelled without prejudice or disclaimer.)
14. (Currently cancelled without prejudice or disclaimer.)
15. (Original) A method for obtaining a biopsy specimen and accessing a remote anatomical site, comprising the steps of:
    a. placing a biopsy device at an anatomical site;
    b. advancing a cannula over the biopsy device;
    c. securing the biopsy specimen; and
    d. withdrawing the biopsy device containing the biopsy specimen from the remote anatomical site, thereby providing access through the cannula to the remote anatomical site.
16. (Original) The method according to claim 15, further comprising the step of positioning a placement means at the remote anatomical site prior to placing the biopsy device.
17. (Original) The method according to claim 15, wherein advancing the cannula comprises the steps of:
    a. coupling a handle means to a cannula; and

b. sliding the cannula coupled to the handle telescopically over the biopsy device.

18. (Original) The method according to claim 15, wherein securing the biopsy specimen comprises the steps of:

a. coupling a handle means to the biopsy device;

b. advancing the biopsy device; and

c. fixing a biopsy specimen in the biopsy device with a securing means.

19. (Original) The method according to claim 18, wherein the securing means severs and retains the biopsy specimen.

20. (Original) The method according to claim 15, further comprising introducing at least one of medicaments, delivery cannula, tissue modification devices, catheters, tubes, diagnostic instruments, and pharmaceuticals and therapeutic agents.